



Supporting Quality Health Care Services at Home

Via FedEx

October 8, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Room 1061
Rockville, MD 20852

Re: **Docket No. 2004D-0443: Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations, Availability**

Dear Sir or Madam:

The American Association for Homecare (AAHomecare) respectfully requests a ninety-day (90-day) extension to the comment period stated in the Notice of Availability for comment on the referenced draft guidance, appearing in the Federal Register on October 4, 2004 at page 59256. Specifically, AAHomecare requests the agency extend the comment period for Docket No. 2004D-0443 – *“Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations”* to March 3, 2005 to permit thorough and thoughtful review, which in turn will permit us to provide commentary that is more meaningful.

AAHomecare’s membership reflects a cross-section of the homecare community, including national, regional, and local providers and suppliers. Our members provide home health services, durable medical equipment and supplies, home infusion and inhalation drug therapies, and rehabilitation and assistive technologies and services to individuals in their homes. With approximately 700 members companies at 3000 locations nationwide, AAHomecare and its members are committed to advancing the value and practice of quality health care services at home. A significant percentage of our members provide medical gases, primarily oxygen (classified as a pharmaceutical subject to 21 CFR Parts 210 and 211 requirements and impacted by the provision of this draft guidance), to respiratory care patients at their residences. AAHomecare will limit its comments to those issues affecting the manufacture and/or distribution of medical gases provided to patients at their residence.

AAHomecare appreciates in advance the consideration of an extension to the comment period deadline on this proposed draft guidance. If you have any questions, please do not hesitate to contact Penelope Solis, Chief of Staff, AAHomecare, via email at penelopes@aahomecare.org or via phone at (703) 535-1893.

Sincerely,

Kay Cox
President & CEO
American Association for Homecare

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